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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,127	10/16/2001	Steven Curtis Zicker	IR 6493-02	3786

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/03/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/978,127	Applicant(s) ZICKER ET AL.	
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

The following is responsive to the request for continued examination under 37 CFR 1.114 of the above-identified application as well as the Preliminary amendment received Aug. 4, 2003.

Claims 1-38 are cancelled without prejudice or disclaimer. New claims 39-43 are added. Claims 39-43 are currently pending.

Information Disclosure Statement

Applicant's Information Disclosure Statement received April 29, 2003 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Claim Objection(s)

Claims 40, 41 are objected to because of the following informalities: In claim 40, line 3, the term "measured" should read –measured--. In claim 41, there are two "." at the end of the claim. Appropriate correction is required.

Claim Rejections—35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 40-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claims 40-43 recite the limitation "the diet" in line 3. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections—35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claim 39 is rejected under 35 U.S.C. 102(a) as being anticipated by Harper, WO 00/44375.

Harper discloses a method for overcoming the problem of oxidative stress in a companion animal such as a dog or cat by increasing the plasma Vitamin E levels in the cat or dog. Specifically, a diet containing Vitamin C and vitamin E are fed to senior (6.5-12.5 years of age) dogs. Harper discloses that such a vitamin "cocktail" will prevent or treat a disorder (aging), which has a component of oxidative stress. Additionally, Harper teaches a method of feeding vitamin E separately to the companion animal in order to increase the Vitamin E levels in the plasma thereby overcoming the problem of oxidative stress. Please see the abstract; page 1, lines 18-21; page 13, line 12; page 16, lines 20-23; Example 19, pages 47-48.

The claim is anticipated by Harper because Harper discloses administration of an identical agent or agents, i.e. Vitamin E and/or C, to an identical host, i.e. aged pets, using the claimed methods steps. Therefore, inhibiting the loss of learning ability or increasing the learning ability of the aged pet would be inherent.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claim 39 is rejected under 35 U.S.C. 102(e) as being anticipated by Hamilton, 6,335,361 B1.

5. Hamilton discloses methods to treat cognition disorders associated with aging. Specifically, the method involves administering an effective amount of a combination of the antioxidants carnitine and α-lipoic acid. A preferred form of carnitine is acetyl-L-carnitine and R-α-lipoic acid. Moreover, Hamilton teaches that the combination of antioxidants may be added to pet food for administration to animals such as cats, dogs, horses, birds and fish. The combination of antioxidants serves to inhibit age-related memory loss and provide improved memory in older subjects. The combination of antioxidants contributes to the improvement of mental acuity. Finally, Hamilton discloses that additional nutrients such as vitamin E or C should be included as they are particularly important in older subjects. Please see col. 6, lines 44-60; col. 7, lines 14-17; col. 8, lines 8-13; col. 10, lines 9-21.

The claim is anticipated because inhibition of the loss of learning ability or the increase in learning ability would be inherent in the antioxidant combination's ability to improve mental acuity and inhibiting age-related memory loss.

With respect to the additional use of coenzyme Q and/or creatine, please note that the claims recite "comprising" language. "Comprising" language, which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). Please see MPEP 2111.03.

In this case, the Examiner respectfully submits that claim 39 is open to the inclusion of the additional ingredients disclosed in Hamilton.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 39 is rejected under 35 U.S.C. 102(b) as being anticipated by Ames et al., 5,916,912.

7. Ames et al. teach a method of increasing the metabolic rate of aged cells of a mammalian host by orally administering an effective amount of a combination of acetyl-L-carnitine and an antioxidant such as lipoic acid (alpha-lipoic acid). Ames et al. disclose that when the combination was administered to old animals, several symptoms

of aging were reversed. Please see col. 1, lines 35-47; col. 2, lines 14-26; col. 3, lines 1-6; col. 4, lines 16-20.

The claim is anticipated by Ames et al. because Ames et al. disclose the administration of identical antioxidants, i.e. alpha-lipoic acid and l-carnitine, to an identical host, an aged animal, using the claimed method steps. Therefore, inhibiting the loss of learning ability or increasing the learning ability of the aged animal would be inherent.

Claim Rejections—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton or Ames et al, supra.

9. Hamilton or Ames et al. do not disclose Applicant's claimed dosage amounts of alpha-lipoic acid and carnitine; however, since Hamilton or Ames et al. establish that effective amounts, i.e. dosage amounts, are necessary to the treatment of disorders/symptoms associated with aging, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the effective amounts of Hamilton or Ames such that the dosage amounts of the carnitine and alpha-lipoic acid are effective to improve mental acuity and to treat or inhibit oxidative stress or symptoms associated with aging in animals.

10. Claims 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harper supra.

11. Harper does not disclose Applicant's claimed dosage amounts of vitamin E and C; however, since Harper establishes that effective amounts, i.e. dosage amounts, are necessary to the treatment of disorders associated with oxidative stress, especially in aging animals, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the effective amounts of Harper such that the

Vitamin E and C are administered in an amount, which is effective to treat disorders associated with oxidative stress.

Conclusion

Claims 39-43 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 703-306-3227. The examiner can normally be reached on Tue-Thur. from 8:30 to 6:00. The examiner can also be reached on alternate Mondays .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725 The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

CDM

Oct. 30, 2003

Cybille Delacroix-Muirheid
Patent Examiner Group 1600